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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,334	HAMMOCK ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-94 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-94 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant is advised that MPEP 2173.05(s) states that, "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m)."

In the instant case, the claims that reference Tables 1-18 do not meet the criteria set forth by MPEP 2173.05(s), as the incorporation creates ambiguity in the claims that would likely be rejected under 35 USC § 112, 2nd paragraph in any subsequent action on the merits. For example, Tables 16 and 18 of the instant specification do not recite any compounds. As such, Tables 16 and 18 have not been included in any group below. Further, several compounds are repeated in multiple tables, and it appears that additional limitations for the tables are present in the text, but not specifically in the Tables generating sufficient confusion in identifying the claimed subject matter.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1-10. Claim 69, drawn to compounds of Groups A-J set forth below, respectively (i.e.- Group 1 is claim 69, reading on Group A, Group 2 is claim 69 reading on Group B, etc.), and pharmaceutical compositions thereof, classified in class 514, subclass 2.

11-20. Claim 17, drawn to a method for inhibiting a soluble epoxide hydrolase with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

21-30. Claim 26, drawn to methods of treating diseases modulated by soluble epoxide hydrolysate with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

31-40. Claim 34, drawn to methods of treating or reducing renal deterioration in a patient with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

41-50. Claim 38, drawn to a method for inhibiting progression of nephropathy in a subject with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

51-60. Claim 43, drawn to methods for reducing blood pressure in a subject with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

61-70. Claim 47, drawn to methods of inhibiting the proliferation of vascular smooth muscle in a subject with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

71-80. Claim 53, drawn to methods of inhibiting the progression of obstructive pulmonary disease, an interstitial lung disease, or asthma in a subject, with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

81-90. Claim 75, drawn to methods for stabilizing biologically active epoxides in the presence of a soluble epoxide hydrolase with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

91-100. Claim 84, drawn to methods for reducing the formation of a biologically active diol produced by the action of a soluble epoxide hydrolase with compounds of Groups A-J set forth below, respetively, classified in class 514, subclass 2.

101-110. Claim 93, drawn to methods for monitoring the activity of a soluble epoxide hydrolase with compounds of Groups A-J set forth below, respetively, classified in class 435, subclass 4.

Each Group (xx1-x10) *supra* corresponding to a specific set of compounds A-J:

A. Table 1; Table 2: compounds 772, 791 and 297; Table 13: compounds 297 and 425; and Table 17.

B. Table 2: compounds 789, 790 and 686; Tables 4, 6, 7, 11, and 14; Table 12: compounds 805, 806 and 811-814; and Table 13: compounds 686 and 687.

C. Table 5.

D. Table 8: compounds 859 and 860.

E. Table 8: compounds 861, 863, 904, 909, 909-1 and 909-2.

F. Tables 9 and 10.

G. Table 12: compound 807.

H. Table 12: compound 808.

I. Table 12: compound 809.

J. Table 12: compound 810.

Claims 58-68 and 70-72 link(s) inventions 1-10. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 58-68 and 70-72.

Claims 1-16 link(s) inventions 11-20. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-16.

Claims 18-25 and 27-29 link(s) inventions 21-30. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 18-25 and 27-29.

Claims 30-33 and 35 link(s) inventions 31-40. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 30-33 and 35.

Claims 36, 37 and 39 link(s) inventions 41-50. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 36, 37 and 39.

Claims 40-42 and 45 link(s) inventions 51-60. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 40-42 and 45.

Claim 45 link(s) inventions 61-70. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 46.

Claims 48-52 and 54-57 link(s) inventions 71-80. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 48-52 and 54-57.

Claims 73, 74 and 76-81 link(s) inventions 81-90. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 73, 74 and 76-81.

Claims 82, 83 and 85-90 link(s) inventions 91-100. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 82, 83 and 85-90.

Claims 91, 92 and 94 link(s) inventions 101-110. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 91, 92 and 94.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions 1-10 and 11-110 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case as evidenced by the claims themselves, one can practice the

methods with a myriad of distinct compounds, and one can use the compounds in various methods.

Further, one could inhibit sEH with diuron; one could treat a disease modulated by sEH, e.g. arthritis, with prednisone; one could treat renal deterioration with lanapril; one could inhibit the progression of nephropathy with N-(3,4-dimethoxycinnamoyl) anthranilic acid; one could reduce blood pressure, with furosemide; one could inhibit the proliferation of vascular smooth muscle with estrogen; one could inhibit the progression of asthma with fluticasone; one could stabilize biologically active epoxides and reduce the formation of diol with diuron; one could monitor the activity of sEH with diuron.

Inventions 1-10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to compounds having distinct structures one from another, and would be expected to have different effects in a biological context.

Inventions 11-110 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods with different end results, e.g. reducing blood pressure and inhibiting the progression of nephropathy, and require the use of different compounds, and in practicing one method one would not necessarily be practicing another.

Inventions 1 and 12-20, 22-30, 32-40, 42-50, 52-60, 62-70, 72-80, 82-90, 92-100 and 102-110 are unrelated.

Inventions 2 and 11, 13-21, 23-31, 33-41, 43-51, 53-61, 63-71, 73-81, 83-91, 93-101 and 103-110 are unrelated.

Invention 3 and 11, 12, 14-22, 24-32, 34-42, 44-52, 54-62, 64-72, 74-82, 84-92, 94-102 and 104-110 are unrelated.

Invention 4 and 11-13, 15-23, 25-33, 35-43, 45-53, 55-63, 65-73, 75-83, 85-93, 95-103 and 105-110 are unrelated.

Invention 5 and 11-14, 16-24, 26-34, 36-44, 46-54, 56-64, 66-74, 76-84, 86-94, 96-104 and 106-110 are unrelated.

Inventions 6 and 11-15, 17-25, 27-35, 37-45, 47-55, 57-65, 67-75, 77-85, 87-95, 97-105 and 107-110 are unrelated.

Inventions 7 and 11-16, 18-26, 28-36, 38-46, 48-56, 58-66, 68-76, 78-86, 88-96, 98-106 and 108-110 are unrelated.

Inventions 8 and 11-17, 19-27, 29-37, 39-47, 49-57, 59-67, 69-77, 79-87, 89-97, 99-107, 109 and 110 are unrelated.

Inventions 9 and 11-18, 20-28, 30-38, 40-48, 50-58, 60-68, 70-78, 80-88, 90-98, 100-108 and 110 are unrelated.

Inventions 10 and 11-19, 21-29, 31-39, 41-49, 51-59, 61-69, 71-79, 81-89, 91-99 and 101-109 are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to products which are structurally distinct from the compounds used in the methods as grouped and

are not required for the methods to be practiced as grouped. Further, each compound would be expected to have a different effect if used in the methods and have a different mode of operation due to the diverse structures.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Additionally, the compounds of the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. The search for the distinct compounds is conducted based on their chemical structure. Therefore, the search of one chemical structure would not necessarily lead to the discovery of another structure, nor would it necessarily lead to the discovery of methods of using and/or making.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

Claims 1-110 are generic to a plurality of disclosed patentably distinct species comprising compounds of formulae (I) and (II), including the species of Tables 1-15 and 17.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. In order to effect a complete response, Applicant must elect a single fully described species, wherein each moiety is specifically defined. Election of a generic

formula, or a formula with generic moieties (i.e. 'alkyl', 'heterocycle', etc.) would be held as nonresponsive.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Rejoinder Practice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/24/07
ANISH GUPTA
PRIMARY EXAMINER

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Art Unit 1654